

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Siegfried ANSORGE et al.

Serial No.: 10/584,072 Group Art Unit: Unknown

Filed: June 22, 2006 Examiner: Unknown

For: USE OF AT LEAST ONE EFFECTOR OF GLUTATHIONE METABOLISM TOGETHER WITH  $\alpha\textsc{-}\textsc{Lipoic}$  acid for the treatment of chronically obstructive lung diseases

## INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

## Timing and Fees

| $\boxtimes$ | Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this informatio disclosure statement is filed: |                                                                                                                                                                       |  |  |
|-------------|----------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|
|             |                                                                                                                      | within three months of the filing date of a national application other than a CPA under § 1.53(d);                                                                    |  |  |
|             |                                                                                                                      | within three months of the actual filing date of the national phase of a PCT application; OR                                                                          |  |  |
|             | $\boxtimes$                                                                                                          | before the mailing of a first substantive office action (including after filing of an RCE).                                                                           |  |  |
|             |                                                                                                                      | 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods ted in 37 C.F.R. § 1.97(b), but before the mailing date of:                     |  |  |
|             |                                                                                                                      | a final rejection under 37 C.F.R. 1.113; termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR a notice of allowance under 37 C.F.R. § 1.311; and |  |  |

|         |             | is acco    | ompanied by:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|---------|-------------|------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|         |             |            | the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR                                                                                                                                                                                                                                                                                                                                                                                                                          |
|         |             |            | a check covering the fee of \$180.00 under 37 C.F.R. § 1.17(p).                                                                                                                                                                                                                                                                                                                                                                                                                              |
|         |             |            | R. § 1.97(d), this information disclosure statement is filed after the mailing lowing actions which have not been withdrawn:                                                                                                                                                                                                                                                                                                                                                                 |
|         |             | a final    | action under 37 C.F.R. § 1.113;                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|         |             | termin     | ation of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2);                                                                                                                                                                                                                                                                                                                                                                                                                             |
|         |             | OR a r     | notice of allowance under 37 C.F.R. § 1.311;                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|         | AND i       | is filed o | on or before payment of the issue fee; AND is accompanied by:                                                                                                                                                                                                                                                                                                                                                                                                                                |
|         |             |            | tement as specified in 37 C.F.R. § 1.97(e) as set forth below, and the fee of 00 under 37 C.F.R. § 1.17(p).                                                                                                                                                                                                                                                                                                                                                                                  |
| Staten  | nents Ur    | nder 37    | C.F.R. 1.97(e)                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|         |             |            | Each item of information contained in this information disclosure<br>statement was cited in a communication from a foreign patent office in a<br>counterpart foreign application having a mailing date not more than three<br>months prior to the filing date of this information disclosure statement; or                                                                                                                                                                                   |
|         |             |            | No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement. |
| Cited 1 | Materia     | <u>ls</u>  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|         |             | anceste    | s of materials listed but not attached were cited in benefit (35 U.S.C. § 120) or application Serial No, on Form 892 by the Examiner and/or Form by the applicant; see 37 C.F.R. § 1.98(d).                                                                                                                                                                                                                                                                                                  |
|         |             | _          | s of materials listed but not attached were cited in an international search dated                                                                                                                                                                                                                                                                                                                                                                                                           |
|         | $\boxtimes$ | Not re     | quired by 37 CFR § 1.98.                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|         | $\boxtimes$ | Copies     | s of the materials listed are attached (except for the foregoing).                                                                                                                                                                                                                                                                                                                                                                                                                           |
|         |             |            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |

| Non-E | nglish l  | Language References                                                                                                                                                          |
|-------|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       |           | An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).                           |
|       |           | A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:                                           |
|       |           | <ul> <li>X = document of particular relevance when it is taken alone</li> <li>Y = document of particular relevance when it is combined with another such document</li> </ul> |
|       |           | A = document defining the general state of the art                                                                                                                           |
|       |           | O = non-written disclosure P = intercalated document                                                                                                                         |
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|       |           | E = patent document which has the benefit of a date earlier than the filing date and which was published only on or after this filing date                                   |
|       |           | D = cited in the application                                                                                                                                                 |
|       |           | L = cited for another reason<br>& = publication of member of same patent family                                                                                              |
|       |           | & - publication of member of same patent failing                                                                                                                             |
|       |           | Translation of other relevant information on foreign search report                                                                                                           |
| Other | Informa   | <u>ution</u>                                                                                                                                                                 |
| Pavme | ent of Fe | ees Due (If Any):                                                                                                                                                            |
|       |           | ck for \$ covering the fee identified above is attached.                                                                                                                     |
|       | Please    | charge to Deposit Account No. 13-3402 \$ for the fee identified above.                                                                                                       |

The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account #13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,

Anthony J. Zelano, Reg. No. 27,969 Attorney/Agent for Applicants

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
Arlington Courthouse Plaza I 2200 Clarendon Blvd. Suite 1400 Arlington, Virginia 22201 Telephone: (703) 243-6333 Facsimile: (703) 243-6410

Attorney Docket No.: PMP-0003

Date: September 28, 2006

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| Substitute | for form 1449A/PT | ro           |          |                        | Complete if Known        |  |
|------------|-------------------|--------------|----------|------------------------|--------------------------|--|
|            |                   |              |          | Application Number     | 10/584,072               |  |
| INFO       | RMATION           | I DISCI      | LOSURE   | Filing Date            | June 22, 2006            |  |
| STAT       | EMENT E           | SY APP       | LICANT   | First Named Inventor   | Siegfried ANSORGE et al. |  |
|            |                   |              |          | Group Art Unit         | Unknown                  |  |
| (          | use as many sh    | neets as nec | cessary) | Examiner Name          | Unknown                  |  |
| Sheet      | 1                 | of           | 2        | Attorney Docket Number | PMP-0003                 |  |

|                        | U.S. PATENT DOCUMENTS |                                                                              |    |                                                      |            |  |  |  |  |
|------------------------|-----------------------|------------------------------------------------------------------------------|----|------------------------------------------------------|------------|--|--|--|--|
| Examiner<br>Initials * | Cite No.1             | U.S. Patent Document   Kind Code <sup>2</sup>   Cite No.   Number (if known) |    | Kind Code <sup>2</sup> Name of Patentee or Applicant |            |  |  |  |  |
|                        | A1                    | 20040127550                                                                  | A1 | Michael TAEGER et al.                                | 07-01-2004 |  |  |  |  |
|                        | A2                    | 20040138311                                                                  | A1 | Michael TAEGER et al.                                | 07-15-2005 |  |  |  |  |
|                        | А3                    | 4871763                                                                      |    | DR. MEDAUS GmbH & CO.                                | 10-03-1989 |  |  |  |  |
|                        |                       |                                                                              |    |                                                      |            |  |  |  |  |
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| FOREIGN PATENT DOCUMENTS |           |                     |                      |                                              |                                                    |                                                        |                                                                                    |    |
|--------------------------|-----------|---------------------|----------------------|----------------------------------------------|----------------------------------------------------|--------------------------------------------------------|------------------------------------------------------------------------------------|----|
| Examiner<br>Initials*    | Cite No.1 | Office <sup>3</sup> | Foreign Patent Docur | nent<br>Kind Code <sup>5</sup><br>(if known) | Name of Patentee or Applicant of<br>Cited Document | Date of Publication of<br>Cited Document<br>MM-DD-YYYY | Pages, Columns, Lines,<br>Where Relevant<br>Passages or Relevant<br>Figures Appear | T⁵ |
|                          | B1        | DE                  | 101 25 883           | A1                                           | SERUMWERK GmbH                                     | 12-12-2002                                             |                                                                                    | A1 |
|                          | B2        | DE                  | 101 25 882           | A1                                           | ESPARMA GmbH                                       | 12-12-2002                                             |                                                                                    | A2 |
|                          | В3        | DE                  | 35 37 656            | A1                                           | DR. MEDAUS GmbH                                    | 05-22-1986                                             |                                                                                    | А3 |
|                          |           |                     |                      |                                              |                                                    |                                                        |                                                                                    |    |
|                          |           |                     |                      |                                              |                                                    |                                                        |                                                                                    |    |
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| Examiner<br>Signature | Date<br>Considered |  |
|-----------------------|--------------------|--|
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<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached. Number refers to English language corresponding family member.

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Substitute for form 1449A/PTO Complete if Known **Application Number** 10/584,072 INFORMATION DISCLOSURE Filing Date June 22, 2006 STATEMENT BY APPLICANT Siegfried ANSORGE et al. First Named Inventor Group Art Unit Unknown (use as many sheets as necessary) **Examiner Name** Unknown PMP-0003 Sheet of Attorney Docket Number

|                        |           | NON PATENT LITERATURE DOCUMENTS                                                                                                                                                                                                                                                     |     |
|------------------------|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|
| Examiner<br>Initials * | Cite No.1 | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.                     | T ² |
|                        | C1        | BIEWENGA, G. et al., "Lipoic acid favors thiosulfinate formation after hypochlorous acid scavenging: a study with lipoic acid derivatives," Arch. Biochem. Biophys., 1994, vol. 312 no. 1, pgs. 114-120.                                                                            |     |
|                        | C2        | TERAMOTO, S. et al., "Effects of angiotension-conversting enzyme inhibitors on spontaneous harvested from patients with or without chronic obstructive pulmonary disease," Jpn. J. Pharmacol., 2000, vol. 83, pgs. 56-62.                                                           |     |
|                        | СЗ        | MALERBA, M. et al., "effect of twelve-month therapy with oral ambroxol in preventing exacerbations in patients with COPD: double-blind, randomized, multicenter, placebo-controlled study (The AMEJTHIST Trial)," Pulmonary Pharmacology & Therapeutics, 2004, vol. 17, pgs. 27-34. |     |
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| Examiner  | Date       |  |
|-----------|------------|--|
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